

SAFETY DATA SHEET

CBG 37.5



Version 1.0 Revision Date: 24.06.2020 SDS Number: 122000017698 Date of last issue: -
Date of first issue: 24.06.2020

Section 1: Identification

1.1 Product identifier

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HSNO Approval Number : HSR002399

ACVM number : A004633

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company

Elanco New Zealand
88 Shortland Street
1010 AUCKLAND
NEW ZEALAND
+64 0800 352 626
elanco_sds@elanco.com

1.4 Emergency telephone number

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)
or +64-98010034 (local)

Section 2: Hazard identification

GHS Classification

Toxic to Reproduction : 6.8B

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P264 Wash skin thoroughly after handling.

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P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Boric acid	10043-35-3	≥ 2 - < 10
D-gluconic acid, cyclic 4,5-ester with boric acid, calcium salt	Not Assigned	≥ 30 - ≤ 40

Section 4: First-aid measures

- General advice : Take off all contaminated clothing immediately.
You should call the National Poisons Centre if you feel that you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).
- If inhaled : Remove to fresh air.
Call a physician immediately.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
If skin reactions occur, contact a physician.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If swallowed : If swallowed, seek medical advice immediately and show this container or label.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : No information available.

Section 5: Fire-fighting measures

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or car-

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- bon dioxide.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)
- Specific extinguishing methods : Prevent fire extinguishing water from contaminating surface water or the ground water system.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
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Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Use with adequate ventilation.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Place in closed containers. Label for proper disposal.
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Section 7: Handling and storage

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:
Avoid formation of aerosol.
Use with local exhaust ventilation.
Avoid contact with skin, eyes and clothing.
- Hygiene measures : Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!
- Conditions for safe storage : For storage suitable stores with adequate product-reception volume must be used.
During handling local official regulations must be observed in order to avert impairment of water by the product.
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Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
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		exposure)	concentration	
Boric acid	10043-35-3	TWA (Inhalable fraction)	2 mg/m ³ (Borate)	ACGIH
		TWA (Inhalable fraction)	2 mg/m ³ (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m ³ (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m ³ (Borate)	ACGIH

Personal protective equipment

Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection
Material : Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

Remarks : Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection : Safety glasses

Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.
The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.
Wear suitable protective equipment.

Section 9: Physical and chemical properties

Appearance : liquid

Colour : colourless

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Impact sensitivity : No data available

Minimum ignition energy : No data available

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Section 10: Stability and reactivity

Reactivity	:	No data available
Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	No data available
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	Carbon monoxide (CO) Carbon dioxide (CO ₂)

Section 11: Toxicological information

Acute toxicity

Product:

Acute oral toxicity	:	Acute toxicity estimate (ATE): > 5.000 mg/kg Method: Calculation method
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Components:

Boric acid:

Acute oral toxicity	:	LD50 (Rat): 2.660 mg/kg Assessment: The component/mixture is minimally toxic after single ingestion.
Acute inhalation toxicity	:	LC50 (Rat): > 2,12 mg/l Exposure time: 4 h Test atmosphere: dust/mist/aerosol Method: OECD 403 Assessment: No adverse effect has been observed in acute toxicity tests.

Skin corrosion/irritation

Components:

Boric acid:

Species	:	Rabbit
Exposure time	:	24 h
Result	:	No skin irritation

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Serious eye damage/eye irritation

Components:

Boric acid:

Species : Rabbit
Result : No eye irritation
Exposure time : 24 h
Method : OECD 405

Respiratory or skin sensitisation

Components:

Boric acid:

Species : Guinea pig
Method : OECD 406
Result : Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Components:

Boric acid:

Genotoxicity in vitro : Test Type: DNA damage and/or repair
Test system: Hamster V79-cells
Metabolic activation: with and without metabolic activation
Result: negative

Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD 471
Result: negative

Test Type: In vitro gene mutation study in mammalian cells
Test system: mammalian cells
Metabolic activation: with and without metabolic activation
Method: OECD 476
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vivo
Species: Mouse (male and female)
Application Route: Oral
Exposure time: Multiple dose
Method: OECD 474
Result: negative

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Carcinogenicity

Components:

Boric acid:

Species : Mouse
Application Route : Oral
Exposure time : 721 days
Method : OECD 451
Result : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

Boric acid:

Effects on fertility : Test Type: Two-generation study
Species: Rat
Application Route: Oral
Frequency of Treatment: 1 daily
General Toxicity - Parent: NOAEL: 100 mg/kg
General Toxicity F1: NOAEL: 100 mg/kg
General Toxicity F2: NOAEL: 100 mg/kg
Result: No toxicity to reproduction

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Positive evidence of adverse effects on development from human epidemiological studies.

Repeated dose toxicity

Components:

Boric acid:

Species : Rat, male and female
NOAEL : 17,5 mg/kg
LOAEL : 334 mg/kg
Application Route : Oral

Further information

Components:

Boric acid:

Remarks : If swallowed
Nausea
Vomiting
Diarrhoea

Remarks : After absorption of large quantities
Ataxia
drowsiness
Ataxia (uncontrolled movements)

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Section 12: Ecological information

Ecotoxicity

Components:

Boric acid:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 5.600 mg/l
Exposure time: 96 h

LC0 (Lepomis macrochirus (Bluegill sunfish)): > 1,021 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 133 mg/l
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : (Daphnia magna (Water flea)): 53,2 mg/l
Exposure time: 21 d
Test Type: Reproductive toxicity

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Persistence and degradability

Components:

Boric acid:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

Boric acid:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 0,757

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

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Section 13: Disposal considerations

Disposal methods

- Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.
- Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.
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Section 14: Transport information

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

HSNO Approval Number

HSR002399

HSW Controls

Approved handler certificate not required.
HSNO tracking not required.
Refer to EPA user guide to the HSNO control regulations for further information.

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

The components of this product are reported in the following inventories:

NZIoC : On the inventory, or in compliance with the inventory

Section 16: Other information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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ACGIH / STEL : Short-term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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